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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,181

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EXAMINER

LIPITZ, JEFFREY BRIAN

ART UNIT

PAPER NUMBER

3769

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,181	<b>Applicant(s)</b> CYNTHIA ET AL.	
	<b>Examiner</b> JEFFREY B. LIPITZ	<b>Art Unit</b> 3769	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 1/5/2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,7,8,11-13,16,24-27,30,34,38,40-43,46 and 50-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7, 8, 11-13, 16, 24-27, 30, 34, 38, 40-43, 46 and 50-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1/5/2011, 1/5/2011, 1/5/2011, 1/5/2011, 1/5/2011.

## DETAILED ACTION

### ***Response to Arguments***

Applicant's amendments filed January 5, 2010 with respect to the 101 rejections of claims 1, 7, 8, 11-19, 24-27, 34, 38-52 have been fully considered and are persuasive. These rejections have been withdrawn.

Applicant's arguments with respect to the 112 rejections have been fully considered but they are not persuasive. Applicant provides blanket statements with respect to all of the 112 rejections that do not consider each of Examiner arguments. Regarding the 112 rejections, Examiner posed the following questions: How does a user or the processor select an ablative surgical algorithm or update the algorithm? In other words, *on what basis does selecting and updating occur? Why are some data included or excluded when performing these steps? How does the processor weigh the importance of particular data?* The crux of this rejection is how are pre-operative data, post-operative data and predicted post-operative related? An associated explanation for amendments will be the most productive way to persuade Examiner to reconsider prior rejections.

Regarding claim 30, this claim recites elements used in steps that are inherent to previously described steps. The corneal data, correlation data and algorithms must be executed by computer components. How can the method of claim 1 be performed without ALL of the limitations of claim 30? These rejections have largely been maintained.

Applicant's arguments with respect to the prior art rejections have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 8, 11-13, 16, 24-27, 30, 34, 38, 40-43, 46, 50-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. See the response to arguments for details. In addition, if a skilled artisan does not know the relationship and the method does not provide a means to ascertain the relationship, then what relationship is stored in the computer readable medium? What is the output of the correlation? What parameters have pre-determined relationships to predicted outcomes? What are the predicted outcomes and how are they expressed (e.g. stromal thickness, topographical data, curvatures at meridians, etc...). If each of these relationships are empirically derived, then those steps that enable the relationship to be determined must be included. If Applicant has predetermined these relationships, then those relationships/algorithms must be included in the claims to enable the method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 30 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 41, this claim recites a step of receiving *post*-perturbation data concerning the cornea on which the refractive surgery *will* be performed. It is unclear how data can be characterized as post-perturbation data if the surgery has not yet been performed.

Regarding claim 30, this claim recites elements used in steps that are inherent to previously described steps. See the response to arguments for details.

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claims 24, 30, 38, and 40 are rejected under 35 U.S.C. 112, fourth paragraph, as being claims in dependent form that do NOT specify a limitation that further limits the subject matter of the claim from which it depends.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 8, 11-19, 24-27, 30-32, 34, 38-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Rajan et al. (5891131), hereinafter Rajan.

Regarding claims 1, 7, 8, 11-13, 16, 25-27, 41-43, 46, 50, 51 and 53-54, Rajan teaches taking into account pre-operative data from ultrasound analysis (Figure 1) for instance. Rajan teaches an approach to modeling limitations on the system/method so that adjustment or adaptation of the ablation algorithm can be obtained (Abstract and Figure 2). Rajan teaches using finite element analysis to predict surgical outcomes (Col. 12, Lines 4-10), and also using post-operative data (Col. 11, Lines 25-29 and Block 38; Figure 2).

Regarding claim 24, a corneal data receiver and a data integrator are necessary components to accomplish the method of Rajan.

Regarding claims 30, 38 and 40, these claims contain limitations that use elements that are inherent to previously rejected steps. The "interfaces" and a data structure are structural and functional equivalents. "Fields" of a data structure have no patentable weight, since any data storage element will have to store data in a certain number of bits. How many bits does it take to store post-perturbation data? How is it "separated" into its own field? What is a field intended to include? Examiner interprets a memory and a data structure for holding data as structural and functional equivalents.

Regarding claims 34 and 52, Rajan teaches receiving corneal measurements (33; Figure 2), which inherently would require instructions to have been given to obtain these measurements. Likewise, Rajan teaches using an algorithm to come up predicted

post-operative results (Box 37; Figure 2). These algorithms are then modified by error data (38), which includes post-perturbation data.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY B. LIPITZ whose telephone number is (571)270-5612. The examiner can normally be reached on Monday to Thursday, 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on (571)272-4768. The fax phone



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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEFFREY B LIPITZ/  
Examiner, Art Unit 3769

/Henry M. Johnson, III/  
Supervisory Patent Examiner, Art  
Unit 3769